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10/528,224

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Hiroshi Nagai

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EXAMINER

HELM, CARALYNNE E

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,224	Applicant(s) NAGAI ET AL.	
	Examiner CARALYNNE HELM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6 and 9-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/4/08 (3 versions)</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (previously cited) in view of "Shokuhin Kenkyu Seika Jyohou" (previously cited).

Yamamoto et al. teaches a liquid composition (drink) that is the result of dried tea leaves that have been combined with 1 liter of water, yielding an extract that contains epigallocatechin-3-O-(3-O-methyl)gallate (EGCG3"Me) (see paragraphs 24-25 and 39-40; instant claims 1 and 5). This compound is taught to have anti-allergenic properties (see paragraph 20; instant claims 1 and 5). Tea leaves taught to contain EGCG3"Me by Yamamoto et al. and the instant claims include Benihomare, Benifuji, and Benifuki (see paragraph 24; instant claim 1). Although the exemplified preparation does not detail which particular tea leaves are used, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the particular varieties taught by Yamamoto et al. The proportion of solvent to leaves is taught to be 5:1 to 100:1 (see paragraph 25). Yamamoto et al. do not explicitly teach that the tea leaves are ground. Dried tea leaves are known to be quite brittle and susceptible to breakage. Further, the extraction of the leaves would proceed faster if the leaves had a larger surface area, such as when in ground form. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to use ground tea leaves in the extraction process. Yamamoto et al. do not teach that the tea is a Chinese species or the total amount of EGCG3"Me in the tea leaf + extract preparation.

"Shokuhin Kenkyu Seika Jyouhou" (henceforth "Shokuhin") teaches that EGCG3"Me is found in tea leaves and used as an anti-allergenic, where the EGCG3"Me is extracted from Benifuji as well as Oba oolong tea leaves (paragraphs 1 and 2 and figure 2; instant claims 3-4). This reference also teaches the tea (drink) made from the tea leaves as well as the content of EGCG3"Me in several varieties of tea leaves (see paragraph 1 and figure 2). In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Oba oolong as the tea leaves in Yamamoto et al. since it was a known option within their technical grasp and capable of performing the same function as those envisioned. Oba oolong is taught by Shokuhin to contain approximately 0.7% EGCG3"Me (see figure 2). Based on the proportions of solvent and leaves taught by Yamamoto et al, this would yield approximately 70 mg to 1170 mg EGCG3"Me per liter (as calculated by examiner; see instant claims 1 and 4-6). This reference also teaches that Benifuji leaves contain 1.5% EGCG3"Me, based on a dry leaf weight (see figure 2). Here, the concentration of EGCG3"Me would range from 150 mg to 2500 mg EGCG3"Me per liter (as calculated by examiner; see instant claims 1 and 5-6). Routine optimization of the type of leaves and proportion of leaves to solvent to achieve the desired level of EGCG3"Me would have been obvious to one of ordinary skill in the art at the time of the invention. Further, the recitation of the intended use "to daily intake of 3mg to 300mg" and "to daily intake 0.3mg to 3000mg" does not add any structural limitation to the claimed product. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

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distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the product taught by Yamamoto et al. in view of Shokuhin would certainly be capable of fulfilling such a use, it fulfills this limitation. It is additionally noted that Yamamoto et al. also teach dosages of EGCG3"Me that were envisioned within their invention (see paragraphs 34-35). Therefore claims 1 and 3-6 are obvious over Yamamoto et al. in view of Shokuhin.

Claims 1, 3-6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shokuhin in view of Piper et al. (previously cited) and Steinberg (previously cited)

Shokuhin teaches that EGCG3"Me is found in tea leaves and used as an anti-allergenic, where the EGCG3"Me is extracted from Benifuji as well as Oba oolong tea leaves (paragraphs 1 and 2 and figure 2; instant claims 3-4). This reference also teaches the tea (drink) made from the tea leaves as well as the content of EGCG3"Me in several varieties of tea leaves (see paragraph 1 and figure 2). Oba oolong is taught by Shokuhin to contain approximately 0.7% EGCG3"Me and Benifuji leaves to contain 1.5% EGCG3"Me (see figure 2). The presence of a masking agent and a particular amount of leaves to use in a drink preparation is not explicitly taught by the reference.

Piper et al. teach a beverage where ground tea and tea extract are present together (see claim 1). This reference also teaches the presence of masking agent including non-dairy creamer and sweeteners (see page 31 lines 5-18; instant claim 9)

Steinberg teaches tea leaves being sealed in bags for ease of use when placed in water (see column 1 lines 10-11 and column 2 lines 43-45). Steinberg goes on to

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teach that 2.4 grams of dried tea leaves are included in each bag and used to prepare a customary cup of tea which typically measures 6 fluid ounces (see column 2 lines 54-59).

It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to use the configuration taught by Piper et al. for the tea drink taught by Shokuhin where the amount of tea leaves used is as taught by Stenberg since these are known configurations that would have been within the technical grasp of one of ordinary skill in the art. This would then correspond to a drink with 203 mg EGCG3"Me per liter if the Benfuki leaves are utilized (as calculated by the examiner; see instant claims 1 and 5-6). Further, the recitation of the intended use "to daily intake of 3mg to 300mg" and "to daily intake 0.3mg to 3000mg" does not add any structural limitation to the claimed product. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the product taught by Shokuhin in view of Piper et al. and Steinberg would be capable of fulfilling the recited daily dosage, it fulfills this limitation. Therefore claims 1, 3-6 and 9 are obvious over Shokuhin in view of Piper et al. and Steinberg

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shokuhin in view of Piper et al. and Steinberg as applied to claims 1, 3-6 and 9 above, and further in view of Marquardt (previously cited).

Shokuhin in view of Piper et al. and Steinberg make obvious a tea drink that comprises one or more selected from EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and at a concentration of 1mg to 500mg per liter to daily intake of 3mg to 300mg. Instant claim 10 recites a sealed bag that contains this composition. Shokuhin in view of Piper et al. and Steinberg do not teach the drink being present in a bag.

Marquardt teaches a bag-in-box vessel for liquid storage (see abstract). Specifically, they envision tea drink being contained within their taught vessel (see column 2 lines 30-38; instant claim 10). This bag is sealed with a cap at the top and a spigot at the side (see figure 7, column 2 lines 34-36, and column 3 lines 67-68) In view of this teaching it would have been obvious to one of ordinary skill in the art at the time of the invention to put the tea of Shokuhin in view of Piper et al. and Steinberg in the container taught by Marquardt. Thus claim 10 is obvious over Shokuhin in view of Piper et al., Steinberg, and Marquardt.

Claims 1 and 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over VirtualCoffee.com (http://www.virtualcoffee.com/october_2000/brewing_methods.html) in view of Shokuhin and Steinberg.

VirtualCoffee.com teaches the Guywan method of serving tea where the dried tea leaves are combined with hot water and drank without separating the extract from the leaves (see The Guywan section). Dried tea leaves are known to be quite brittle and susceptible to breakage. Further, the preparation of the extract portion of the drink

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would proceed faster if the leaves had a larger surface area, such as when in ground form. This reference does not teach particular types of teas used in this method other than green tea or quantities of tea leaves.

Shokuhin teaches that EGCG3"Me is found in tea leaves and used as an anti-allergenic, where the EGCG3"Me is extracted from Benifuji as well as Oba oolong tea leaves (paragraphs 1 and 2 and figure 2; instant claims 1 and 3-5). This reference also teaches the tea (drink) made from the tea leaves as well as the content of EGCG3"Me in several varieties of tea leaves (see paragraph 1 and figure 2). The Benifuji leaves are taught to contain 1.5% EGCG3"Me, based on a dry leaf weight (see figure 2).

Since the collection of references teach dried tea leaves as well as the tea drink made therefrom, it would have been obvious to use the quantity of leaves taught by Steinberg to prepare the drink of Shokuhin via the Guywan method, a centuries old methodology for drinking tea. This would then correspond to a drink with 203 mg EGCG3"Me per liter (as calculated by the examiner; see instant claims 1 and 5-6). Further, the recitation of the intended use "to daily intake of 3mg to 300mg" and "to daily intake 0.3mg to 3000mg" does not add any structural limitation to the claimed product. Therefore a preparation of ground tea leaves and extract of tea leaves from Benifuji leaves where EGCG3"Me at 3 mg to 300 mg per liter would have been obvious to one of ordinary skill in the art at the time of the invention. Thus claims 1 and 3-6 are obvious over VirtualCoffee.com in view Shokuhin and Steinberg.

Claims 1 and 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over VirtualCoffee.com in view Shokuhin and Steinberg as applied to claims 1 and 3-6 above, and further in view of Piper et al.

VirtualCoffee.com in view Shokuhin and Steinberg make obvious one or more selected from EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and at a concentration of 1mg to 500mg per liter to daily intake of 3mg to 300mg. This modified reference does not teach the presence of a masking agent.

Piper et al. teach a beverage where ground tea and tea extract are present together (see claim 1). This reference also teaches the presence of masking agent including non-dairy creamer and sweeteners (see page 31 lines 5-18; instant claim 9). As a known additive in tea preparations containing both extracts and leaves to improve their flavor, it would have been obvious to one of ordinary skill in the art the time of the invention to include the masking agent of Piper et al. in the composition of VirtualCoffee in view Shokuhin and Steinberg. Therefore claims 1 and 9 re obvious over VirtualCoffee in view Shokuhin, Steinberg, and Piper et al.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over VirtualCoffee.com in view Shokuhin and Steinberg as applied to claims 1 and 3-6 above, and further in view of Marquardt.

VirtualCoffee.com in view Shokuhin and Steinberg make obvious one or more selected from EGCG3"Me, GCG3"Me, EGCG4"Me, GCG4"Me and at a concentration of 1mg to 500mg per liter to daily intake of 3mg to 300mg. Instant claim 10 recites a

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sealed bag that contains this composition. VirtualCoffee.com in view Shokuhin and Steinberg do not teach the drink being present in a bag.

Marquardt teaches a bag-in-box vessel for liquid storage (see abstract). Specifically, they envision tea drink being contained within their taught vessel (see column 2 lines 30-38; instant claim 10). This bag is sealed with a cap at the top and a spigot at the side (see figure 7, column 2 lines 34-36, and column 3 lines 67-68) In view of this teaching it would have been obvious to one of ordinary skill in the art at the time of the invention to put the tea of VirtualCoffee.com in view Shokuhin and Steinberg in the container taught by Marquardt. Thus claim 10 is obvious over VirtualCoffee.com in view Shokuhin, Steinberg, and Marquardt.

Response to Arguments

Applicant's arguments filed February 20, 2009 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The “to daily intake of 3mg to 300mg” and (to daily intake of 0.3mg to 3,000mg” recitations are intended use. A recitation of the intended use of the claimed invention

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must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Nothing precludes the compositions made obvious by the rejections above from serving in the intended capacity (e.g. as food/drink, for a particular daily intake of EGCG3"Me, etc). Since this is the case, the references meet the intended use limitations of the claims. Furthermore, applicant claims a product, not a method of use. Thus prior art references cited need not teach the daily dosage intended by applicant

Applicant asserts that the motivation presented for the inclusion of ground tea leaves in the composition of Yamamoto et al. is erroneous. According to MPEP 2144, "[t]he reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)". One of ordinary skill in the art would be aware that a higher surface area ground tea leaf preparation would be able to be extracted faster than a whole leaf. The logic of applicant's assertion that the same end would be achieved by using an extract to prepare an extract is unclear. Further, since the tea leaves of Yamamoto et al. are taught to be brittle and susceptible to breakage anyway, their presence in ground form would be almost inevitable. In addition, Yamamoto et al. teach a preparation containing tea leaves in a tea extract prior to the purification of the extract,

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thus the inclusion of the leaves in ground form is a small and obvious addition to the teachings provided by the reference (see paragraphs 24-25).

Applicant argues that Shokuhin is not concerned with the amount of EGCG3"Me for use in a food or drink and that the amount of this compound present in a composition composed of a tea extract and ground tea is not equivalent to the amount of this compound in the tea leaves. Quoting directly from Shokuhin, the reference recites, "[n]owadays the search for anti-allergic substances in foodstuffs has been strongly demanded to deal with allergic disorders which have become a serious social problem. Therefore, in order to effectively utilize the epigallocatechin-3-O-(3-O-methyl)gallate (EGCG 3"Me; Fig. 1), an anti-allergic substance found out in tea leaves, an objective of the present invention is to clarify the variation in the content thereof due to the tea variety, tea picking time and tea type prepared therefrom" So this reference is most certainly concerned with the amount of EGCG3"Me in food. Figure 2 shows the amount of EGCG3"Me in several varieties of tea. Since these leaves are the sole source of EGCG3"Me in the tea preparations of made obvious by the rejections above, the amount of EGCG3"Me they contribute is the total quantity of EGCG3"Me in the compositions, whether in extract form or still in the leaves. In the case of Shokuhin in view of Stenberg et al. and Piper, the presence of 2.4 grams of dried tea leaves used to prepare a customary cup of tea which typically measures 6 fluid ounces with the Benifuji leaves, taught to contain 1.5% EGCG3"Me would result in a preparation of ground tea with tea extract containing 203mg EGCG3"Me per liter.

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Applicant argues that Piper et al. does not teach an extract. Piper et al. teach the addition of hot water to a ground preparation of tea leaves, the result of which is an extract of the tea and ground tea leaves (see page 28 line 19-page 29 line 11 and page 30 lines 4-14).

Applicants point to examples 3 and 4 of the instant specification as a written description of the claimed "tea bag". This tea bag is a bag containing a liquid preparation of ground teas leaves and tea extract. As applicant notes, Marquardt teaches a bag that holds a liquid beverage preparation. Since tea is a well known beverage and explicitly envisioned by the reference, it would have been obvious to put the drink preparation of Shokuhin in view of Stenberg et al. and Piper into the bag taught by Marquardt.

In light of the amendments to the claims of copending US Application No. 10/588428, the provisional nonstatutory obviousness-type rejection is hereby withdrawn.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615